# NEWBORN SCREENING PROGRAM

# HANDBOOK


Utah
Department
of Health

STATE OF UTAH
DIVISION OF COMMUNITY AND FAMILY SERVICES
BUREAU OF CHILDREN WITH SPECIAL HEALTH CARE NEEDS

COMPILED BY FAY A KEUNE, RN, BSN

DISTRIBUTED BY UTAH DEPARTMENT OF HEALTH
COMMUNITY & FAMILY HEALTH SERVICES
CHILDREN WITH SPECIAL HEALTHCARE NEEDS
NEWBORN SCREENING PROGRAM

MARCH 2002

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UTAH DEPARTMENT OF HEALTH
NEWBORN SCREENING PROGRAM

# KIT ORDERING

Newborn Screening Kits — Fees Effective November 15, 2001

TWO-PART KIT (First and Second Screen forms) — $31.00

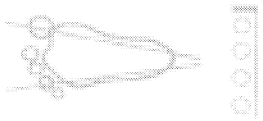
The two-part kits are the initial forms used by the institutions of birth

Order two-part kits from:
Utah Department of Health Laboratory
ATTN: Chris Peper or Wandalee Johnson
46 N Medical Dr
Salt Lake City UT 84113
Phone: (801) 584-8400
Fax: (801) 584-8421

MISCELLANEOUS FORMS — No Charge

Miscellaneous forms are supplied as replacement forms for inadequate specimens, for recall specimens, or for use when the original kit has been lost. The original two-part kit was issued to the parent at the hospital/birthplace.

Order miscellaneous forms from:
Newborn Screening Program
ATTN: Shelley Morrill
44 N Medical Dr
PO Box 144710
Salt Lake City UT 84114-4710
Phone: (801) 584-8256
Fax: (801) 536-0962



# UTAH NEWBORN SCREENING

## INTRODUCTION

This handbook was designed to educate local hospital personnel (nursery staff and laboratory staff), physicians, midwives, and other health care providers about the requirements for newborn screening in Utah. It includes background information on the importance of newborn screening with specific instructions on completing the forms and submitting blood spot specimens.

The purpose of this handbook is to promote a better understanding of the newborn screening forms and the information entered on them. The quality of the newborn screening data and the ability to identify and locate families and medical providers quickly depends heavily on those completing the forms. The institution of birth or the midwife/practitioner providing assistance to the mother at the birth has the responsibility of initiating the newborn screening process.

The program uses the information on the form to determine if the blood spot specimen is adequate for testing and to identify those newborns at high risk for a abnormal result.

## IMPORTANCE OF NEWBORN SCREENING

Utah State Law (UCA 26-10-6) requires all infants born in Utah to be tested.

The scientific and political/social advancements in the United States came together in the same time period to foster the development of the newborn screening practices. In the 1960's, parent advocacy groups were instrumental in getting legislation passed for prevention of mental retardation. In 1965, Utah State legislators adopted mandatory testing of all newborns for phenylketonuria (PKU) and other metabolic diseases that might result in brain damage or death.

## THE STATE HEALTH DEPARTMENT

The Utah Department of Health began managing the newborn screening process in 1979. Congenital hypothyroidism and galactosemia were added to the PKU testing. The Newborn Screening Program is administered under the laws and rules of the State. The Newborn Screening Laboratory at the State Health Laboratory tests all the samples that are submitted. The Newborn Screening Program at the Bureau of Children with Special Health Care Needs provides follow up on abnormal specimens, education to the public and providers, and assists with identification of resources. The lab and the follow up program work together to provide services to the community.

## CONFIDENTIALITY OF NEWBORN SCREENING RECORDS

Newborn Screening staff protect the information on the newborn screening forms from unwarranted or indiscriminate disclosure. Records are available only to persons who are authorized access by State Law and supporting rules. Legal safeguards for the confidentiality of records have been strengthened in recent years. Physicians, hospitals, and families are assured that extensive legal and administrative measures are used to protect individuals from unauthorized disclosure of personal information.

## MEDICAL HOME

The Newborn Screening program supports and encourages the 'Medical Home' concept for all infants. Health care providers must be identified at birth. These providers will be contacted for any follow up needs that occur.

What is a Medical Home?

A m*edical home* is not a building, house or hospital, but rather a family-centered approach to providing health care in a high quality and cost effective manner. Primary care providers, families, and allied health care professionals act as **partners** to identify and access all the medical and non-medical services needed to help children and families achieve their maximum potential. A medical home includes care that is accessible, family-centered, continuous, comprehensive, coordinated, compassionate, and culturally-competent.

The ideal source of a child's medical home is a primary care pediatrician or family doctor working in partnership with the parents. All children deserve a medical home, and this relationship is even more important for children who may have special health care needs. Benefits of a medical home include: increased patient and family satisfaction, establishment of a forum for problem solving, improved coordination of care, enhanced efficiency for children and families, efficient use of limited resources, increased professional satisfaction, and increased child wellness due to comprehensive care. For more information contact Marina Marcroft, RN (801)584-8584 or email mmarcrof@doh.state.ut.us

## SPECIFIC RESPONSIBILITIES

### FIRST SCREEN SPECIMEN

Hospital personnel, midwives, and birth attendants must complete the personal data required on the form and must collect and submit a testable blood specimen. Necessary procedures may cut across departmental lines. These procedures when combined with the current emphasis on reducing the length of stay in hospitals, make it extremely important for one hospital staff member to be given the overall responsibility and authority to request and obtain the cooperation needed. Specifically, the following should be done:

- Develop efficient procedures for prompt assignment of a Newborn Screening Kit, preparation of data, and collection of filter paper blood spot specimen on every newborn. [R398-1]

- Collect and record the information requested on the data portion of the first screen form - infant name, sex, feeding, adoption, transfusion, date of birth, mother's name, address, and phone number, mother's date of birth, health care provider. [R398-1-8 (e)]

- Prepare a legible form, making certain that every item is completed and correct. Print in block, capital letters using black ink. Completion of second screen form at this time is discouraged. Many items change before the second specimen is collected.

- Collect an appropriate blood spot specimen using the heel stick method. The person who is drawing the specimen must complete the 'Date of Specimen' on the form. Timing of collection should be between 48 hours and five days of age. [R398-1-8] [R398-1- 5] Use of capillary tubes to transfer blood to the filter paper is not recommended. Capillary tubes tend to roughen the filter paper and cause over absorption.

- If possible, collect the specimen prior to a transfusion. [R398-1-5 (2)]

- Allow specimen to dry, horizontally in room air, for 3 hours.

- Transport specimen within 24 hours of collection to the Newborn Screening Lab. If possible, using a courier is highly suggested to decrease delay in receipt of specimen and testing. [R398-1-8 (2)]

- Educate the family regarding the required screening, which disorders are screened, and how to obtain the second screen collection . [R398-1-6]

- Develop efficient procedures for prompt collection of the filter paper blood spot specimen on the newborn whose specimen was determined to be abnormal or unsatisfactory for testing (could not test). [R398-1-9] [R398-1-10]

SECOND SCREEN SPECIMEN

Utah law requires all newborns to have a second specimen drawn between 7 and 28 days of age. These specimens are usually collected during the first visit to the pediatrician or health care provider. Office staff, clinic staff and midwives must assemble and record the personal data to be entered onto the forms and must collect and submit a testable blood specimen. Specifically, the following should be done:

- Develop efficient procedures for preparation of data and collection of filter paper blood spot specimen on every newborn. [R398-1]

- Collect and record the information requested on the data portion of the second screen form - infant name, sex, feeding, adoption, transfusion (if applicable), date of birth, mother's name, address, and phone number, mother's date of birth, health care provider. [R398-1-8 (e)]

- Prepare a legible form, making certain that every item is completed and correct. Print in block, capital letters using black ink.

- Collect an appropriate blood spot specimen using the heel stick method. The person who is drawing the specimen must complete the 'Date of Specimen' on the form. Timing of collection should be between 7 and 28 days of age. There are exceptions. [R398-1-8] [R398-1-5] Use of capillary tubes to transfer blood to the filter paper is not recommended. Capillary tubes tend to roughen the filter paper and cause over absorption.

- If possible, collect the specimen prior to a transfusion. [R398-1-5 (2)] If transfusion has been given, collect specimen 7 - 10 days after the transfusion.

- Allow specimen to dry, horizontally in room air, for 3 hours.

- Transport specimen within 24 hours of collection to the Newborn Screening Lab. If possible, using a courier is highly suggested to decrease delay in receipt of specimen and testing. [R398-1-8 (2)]

- Develop efficient procedures for prompt collection of filter paper blood spot specimen on the newborn whose specimen was determined to be abnormal or unsatisfactory (could not test). [R398-1-9] [R398-1-10]

## GENERAL INSTRUCTIONS FOR SUBMITTING THE NEWBORN SCREENING FORM

- Follow the instructions that come with the newborn screening kit.
- Print legibly, in block letters, using black ink.
- Avoid abbreviations, except the standard abbreviations used in addresses (use those acceptable from the US Postal Service).
- Verify with the mother (or informant) the spelling of names, especially those that have different spellings for the same sound (Smith or Smyth, Gail or Gayle, and Wolf, Wolfe, or Woolf, etc.).
- Use the current form designated by the State. The filter paper is a Food and Drug Administration (FDA) regulated form. The filter paper has a shelf-life of two years, after printing. *All forms are identified with the expiration date.*
- Always avoid touching the filter paper. Moisture, body oil, hand lotion, powder from gloves, and even compression of the filter paper fibers can interfere with the absorption of the blood and test results.
- Complete all requested data fields.
- Instruction copy is to be removed prior to collecting the specimen. It may be kept for your records.

The testing for the Newborn Screen is considered to be "moderate or high complexity testing, or both" by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Newborn Screening Laboratory must comply with the CLIA regulations, specifically Subpart J. This includes CLIA's minimum data that must be collected to be in compliance.

The requested data is designed to identify an infant, family, and health care provider in compliance with federal regulations. Although these disorders are rare, the impact of them on an individual and family can be tremendous. Correctly identifying the infant and rapidly notifying the health care provider is important when there are abnormal results. Time is critical in getting the initial evaluation done and treatment started. Nationally, it is the standard of care to identify the infant, complete confirmatory testing, and begin treatment prior to 21 days of age.

- Collect a blood specimen by the heel stick method. Use of capillary tubes to transfer blood to the filter paper is not recommended. Capillary tubes tend to roughen the filter paper and cause over absorption. [Appendix ]
- Dry specimen thoroughly, 3-4 hours in room air, before mailing. Specimen should be dried in a horizontal position. A rack designed for this purpose is available, free of charge, through the Program.

- Submit the specimen to the Newborn Screening Laboratory within 24 hours of the specimen collection. Use of a courier is recommended to reduce delay in transportation and testing times. If using the US Postal system, the regulations/standards for mailing clinical specimens apply.

- A Tyvek® envelope has been supplied with the kit for use by the family/health care provider for the second screening specimen.

## ITEM BY ITEM INSTRUCTIONS FOR COMPLETING THE DEMOGRAPHIC PART OF THE NEWBORN SCREENING FORM

**PLACE LABEL HERE**
**FOR UDOH LAB ONLY-DO NOT MARK**

Leave this box blank. It is used by the Newborn Screening Lab for the accession number and bar code.

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**Sample collection date (Month, Day, Year)**

Enter the sample collection date as eight digits. The first two digits for month, two digits for day, and 4 digits for year. Use leading zeros, if necessary. For example: 04-01-2001 for April 1, 2001.

*This date establishes the parameter determining whether or not the specimen has been received within the acceptable time frame for testing. Enzymes and metabolites begin to break down the minute the specimen is drawn. The older the specimen is when received for testing, the less likely the level of enzymes and metabolites will be accurate. The lab cannot guarantee results on a specimen that has been received outside of the acceptable time frame.*

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**Medical Record Number**

Alpha or numeric digits may be entered.

*This space is supplied at the request of the providers to assist in filing the results in the chart. This information may be the hospital medical record number or the health care provider medical record number (2nd screen specimens).*

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**Baby's last name**

Enter the baby's last name(s). The baby's last name does not need to be the same as the mother's last name. Hyphens and apostrophes are acceptable. *This field will accept up to 12 characters.*

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**Baby's first name**

Enter the baby's first name. If a first name has not been selected, leave this field blank. **Do not enter 'baby girl,' 'girl,' 'bg,' 'baby boy,' 'boy,' 'bb,' or sex and mother's first name.** You may enter

'twin A,' 'triplet C,' etc. *This field will accept up to 6 characters.*

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**Sex**

Check M (male) or F (female) box.

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**Birthplace/Hospital**

Enter place where baby was born. You may enter a hospital name, birth institution name, 'home birth,' 'out of state' [if born in another state], 'other' [usually precipitous birth occurring in a moving conveyance or at a non-facility], or 'unknown.'

*This information is used to determine where the first screening results are to be sent. This information helps identify a baby from another born on the same day with the same last name and sex. The place of birth is a reference source for information. It is used in statistical reports to determine the number and/or percent of Utah babies screened.*

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**Baby's Birthdate**

Enter the baby's birth date as eight digits. The first two digits for month, two digits for day, and 4 digits for year. Use leading zeros, if necessary. For example: 04-01-2001 for April 1, 2001.

*This information is used for identification, quality assurance issues, and diagnostic purposes.*

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**Individual items**

Check any and all boxes that apply to the newborn:

Breast (feeding)
Bottle (feeding)

Adopted

Adoption issues may cause some confusion. The Newborn Screening Program maintains patient and record confidentiality. The first screen form must be completed with information to identify the baby and health care provider. If there is concern about entering the birth mother's information, the adoptive agency or adoptive mother's information may be entered. Contact person must be entered. [R398-1-8 (e)] The second screen form and education should be given to the adoptive agent or

adoptive parents with instructions for collection and submission of the second screen specimen. Do not fill out the information on the second screen card. The card should be completed at the health care provider's office with the adoptive names entered.

Premature/sick

Transfusion; enter date of transfusion

Transfusions prior to first screening specimens invalidate results for galactosemia and hemoglobinopathy. Transfusions given 7-10 days prior to second screening specimens could interfere with the results for phenylketonuria and congenital hypothyroidism. *This information is used in interpretation of the screening results, as well as diagnosis and treatment. Babies who have received transfusions may have results that are not valid and will need another specimen drawn at a later date.*

**Birthweight (gms)**

Enter the baby's birth weight in grams. *This field will accept up to 4 characters.* Use leading zeros if necessary.

**Mother's last name**

Enter the mother's legal last name(s). *This field will accept up to 12 characters.* If the mother is unmarried, the last name and maiden name can be the same.

**Mother's first name**

Enter the mother's first name. *This field will accept up to 8 characters.*



**Mother's maiden name**

Enter mother's maiden name, even if it is the same as the legal last name(s). *This field will accept up to 12 characters.* The maiden name is used for identification purposes



**Mother's mailing address**

Enter the mother's usual mailing address. A P.O. Box or drawer is acceptable. Include apartment number, lot number, etc. *This field will accept up to 20 characters.*

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**City**

Enter the mother's city. *This field will accept up to 11 characters.*

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**State**

Enter mother's state. Use the 2-digit abbreviation. *This field will accept up to 2 characters.*

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**Zip**

Enter mother's zip code. *This field will accept up to 5 characters.*

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**Mother's Birthdate**

Enter mother's birth date as 8 digits. Two digits for the month, two digits for the day, and 4 digits for the year. Leading zeros are required. For example: 04-01-2001 for April 1, 2001.

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**Mother's Area Code & phone**

Enter the mother's phone number, including the area code. *This field will accept up to 10 characters.*

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**Doctor/Clinic Name**

Enter the name, last and first, of the health care provider or clinic that will provide health care to the newborn. *This field will accept up to 21 characters.* The information distinguishes providers with the same name.

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**Doctor/Clinic Address**

Enter the address of the health care provider or clinic that will provide health care to the newborn.

*This field will accept up to 21 characters.* This information identifies health care providers that have the same last name by identifying the clinic where the physician is located (some providers work at two or more clinics).

**City**

Enter the city of the health care provider or clinic that will provide health care to the newborn. *This field will accept up to 12 characters.*

**State**

Enter the state of the health care provider or clinic that will provide health care to the newborn. Use the 2-digit abbreviation. *This field will accept up to 2 characters.*

**Zip**

Enter the zip of the health care provider or clinic that will provide health care to the newborn. *This field will accept up to 5 digits.*

**Doctor/Clinic Area Code & Phone**

Enter the phone number of the health care provider or clinic that will provide health care to the newborn, including the area code. *This field will accept up to 10 characters.*

**Recall Screen Mark Only If Instructed**

Mark this area only when instructed by the program staff. When this area is marked, the lab staff are able to identify the recall specimen from the routine specimen.

# SPECIAL INSTRUCTIONS

## Abnormal Results

Program staff will call the doctor/clinic noted on the demographic form for all abnormal results. Instructions will be given for follow up. You may be asked for the collection of the usual second specimen or for additional confirmation testing. If there are any questions, call the program for clarification (801-584-8256).

## Miscellaneous Forms

Miscellaneous forms are supplied without cost as replacement forms for inadequate specimens, for recall specimens, or for use when the original kit form has been lost. (The original kit was issued to the parent at the hospital/birthplace.)

- Write the original Kit ID Number on the top of the miscellaneous form. This original kit number was issued by the hospital of birth and can usually be obtained from the Kit ID log kept in the nursery.

- Mark the 'Test Requested' box for the appropriate screen needed. *Please mark if you are requesting a first or a second screen.*

- The 'Recall Screen' box is to be marked only if you have been instructed to do so by the program. It is used to notify the lab of the need for the recall specimen procedure and testing.

## Transfusion

Transfused blood adds foreign red blood cells [adult hemoglobin] to the infant's circulation thereby altering the level of fetal hemoglobin and enzymes found in the blood. Therefore infants who have received transfusions containing red blood cells may not have an accurate screen. In addition, dialysis and plasma exchange transfusions may temporarily reduce the concentration of circulating metabolites and hormones for phenylketonuria (PKU) or hypothyroidism. This change may result in a false negative screen for PKU or a false positive screen for hypothyroidism.

- Always try to collect the first specimen prior to transfusion.

- If first specimen is collected after a transfusion, another specimen will needed when the foreign red blood cells are no longer circulation (approximately 120 days after the last transfusion given).

- Collect second specimen 7-10 days after the last transfusion.

- Program staff will follow up on all specimens with the Transfusion box marked

  and/or

  if the hemoglobinopathy results are indicative of a transfusion (newborn's results will show a predominance of 'A' [adult] hemoglobin).

  A review of medical records and the transfusion history will be necessary. If transfusion(s) is documented, instructions will be given for further action.

Unsatisfactory Specimens

The Utah State Lab receives blood spot specimens in conditions that are unsatisfactory for testing. Unsatisfactory specimens are known to give invalid results. Submitting unsatisfactory specimens can result in delays, placing the newborn at risk. *Each specimen is reviewed by trained staff to determine if it is acceptable for testing or not.*

***If the specimen is determined to be unsatisfactory, the Newborn Screening tests are not done. The newborn's status - normal or abnormal - is unknown.***

- Develop efficient procedures for recalling newborns, preparation of data, and collection of filter paper blood spot specimen on the unsatisfactory specimen.

- Notification letter, specimen rejection form [mailer], and a replacement miscellaneous newborn screening form are sent to the hospital/birth institution on unsatisfactory **First** Screening Specimens. [R398-1-4]

- Notification letter, specimen rejection form [mailer], and a replacement miscellaneous newborn screening form are sent to the health care provider on unsatisfactory **Second** Screening Specimens. [R398-1-7]

- Collect specimen for unsatisfactory first and routine second specimens on different days, at least two weeks apart.

# BIRTH RECORD NUMBER

The Utah Department of Health is legally required to collect three distinct data sets for each birth that occurs in Utah: Newborn Screening (heel-stick) data, Newborn Hearing data, and the Birth Certificate data. The Department is looking for ways to simplify and unify this effort.

Goals:

- Link the three data sets together with a single unique number
- Increase the accuracy of the data being collected
- Improve heath status of newborns through enhanced follow-up activities
- Locate newborns missed in screening
- Identify newborns lost to follow up
- Decrease/eliminate unnecessary contact of families on newborns that have died

One of the solutions to simplify newborn data collection is to link the three data collection systems together. This linkage will be done by identifying each of the data sets with a 'birth record number'. The Newborn Screening (heel stick) kit ID number, which is assigned to each Utah newborn, has been chosen as this number. The number is seven digits, alpha and numeric, in length. There are no spaces or hyphens in the number. The Newborn Screening kit will include a set of stick-on labels on the first screening form, bearing the Newborn Screening ID number. The labels can be placed on the other records. The Hearing Screening and Birth Certificate databases have created a field to accept the Birth Record Number.

<u>Instructions:</u>

- Assign the 'birth record number' for the newborn. This is the Newborn Screening kit number.
- Place this 'birth record number' label on the birth certificate worksheet, the Hearing Screening log, and the Newborn Screening log.
- Enter the Birth Record Number into the databases:

  for Hearing Screening: Hi*Track database: use the 'Alternate record #' field.
  Hi*Screen: use the 'Medical ID' field.

  for Birth Certificate database: use the 'Newborn Screening number' field

- If the first Newborn Screening form becomes contaminated or unusable for any reason, use a miscellaneous form. Enter the original kit number (one of the 'birth record number' labels could be applied over the miscellaneous number) and mark the 'Test Requested' box as First Screen. Collect blood specimen.

- If the newborn dies prior to obtaining the Newborn Screen: it is not necessary to assign a 'birth record number'. Enter "deceased" into the 'Newborn Screening number' field on the Birth Certificate, and into the inpatient screening results field of the Hi*Track hearing screening database.

- Transfer of newborn to another institution:

  1) If transferred prior to assigning the 'birth record number':
     a) Enter "transferred" in to the 'Newborn Screening number' field on the Birth Certificate.
     b) The receiving hospital is responsible for assigning the 'birth record number', collecting the Newborn Screen First Specimen, and entering that 'birth record number' into the Hearing Screening database.

  2) If transferred after assigning the 'birth record number' and collecting the Newborn Screening First Specimen, but before the hearing screen is done:
     a) Notify the receiving nursery that the newborn screening first screen has been done and the assigned 'birth record number' number.
     b) The receiving nursery is responsible to enter the 'birth record number' into the Hearing Screening database.

# Newborn Screening Statute

26-10-6. Testing of newborn infants.

(1) Except in the case where parents object on the grounds that they are members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section, each newborn infant shall be tested for:

(a) phenylketonuria (PKU);

(b) other metabolic diseases which may result in mental retardation or brain damage and for which:

(i) a preventive measure or treatment is available; and

(ii) there exists a reliable laboratory diagnostic test method; and

(c) (i) beginning July 1, 1998, for an infant born in a hospital with 100 or more live births annually, hearing loss; and

(ii) beginning July 1, 1999, for an infant born in a setting other than a hospital with 100 or more live births annually, hearing loss.

(2) In accordance with Section 26-1-6, the department may charge fees for:

(a) materials supplied by the department to conduct tests required under Subsection (1);

(b) tests required under Subsection (1) conducted by the department;

(c) laboratory analyses by the department of tests conducted under Subsection (1); and

(d) the administrative cost of follow-up contacts with the parents or guardians of tested infants.

(3) Tests for hearing loss under Subsection (1) shall be based on one or more methods approved by the Newborn Hearing Screening Committee, including:

(a) auditory brainstem response;

(b) automated auditory brainstem response; and

(c) evoked otoacoustic emissions.

(4) Results of tests for hearing loss under Subsection (1) shall be reported to:

(a) parents when results of tests for hearing loss under Subsection (1) suggest that additional diagnostic procedures or medical interventions are necessary; and

(b) the department.

(5) (a) There is established the Newborn Hearing Screening Committee.

(b) The committee shall advise the department on:

(i) the validity and cost of newborn infant hearing loss testing procedures; and

(ii) rules promulgated by the department to implement this section.

(c) The committee shall be composed of at least 11 members appointed by the executive director, including:

(i) one representative of the health insurance industry;

(ii) one pediatrician;

(iii) one family practitioner;

(iv) one ear, nose, and throat specialist nominated by the Utah Medical Association;

(v) two audiologists nominated by the Utah Speech-Language-Hearing Association;

(vi) one representative of hospital neonatal nurseries;

(vii) one representative of the Early Intervention Baby Watch Program administered by the department;

(viii) one public health nurse;

(ix) one consumer; and

(x) the executive director or his designee.

(d) Of the initial members of the committee, the executive director shall appoint as nearly as possible half to two-year terms and half to four-year terms. Thereafter, appointments shall be for four-year terms except:

(i) for those members who have been appointed to complete an unexpired term; and

(ii) as necessary to ensure that as nearly as possible the terms of half the appointments expire every two years.

(e) A majority of the members constitute a quorum and a vote of the majority of the members present constitutes an action of the committee.

(f) The committee shall appoint a chairman from its membership.

(g) The committee shall meet at least quarterly.

(h) (i) (A) Members who are not government employees shall receive no compensation or benefits for their services, but may receive per diem and expenses incurred in the performance of the member's official duties at the rates established by the Division of Finance under Sections 63A-3-106 and 63A-3-107.

(B) Members may decline to receive per diem and expenses for their service.

(ii) (A) State government officer and employee members who do not receive salary, per diem, or expenses from their agency for their service may receive per diem and expenses incurred in the performance of their official duties from the committee at the rates established by the Division of Finance under Sections 63A-3-106 and 63A-3-107.

(B) State government officer and employee members may decline to receive per diem and expenses for their service.

(i) The department shall provide staff for the committee.

Amended by Chapter 162, 1998 General Session

**R398. Health, Community and Family Health Services, Children with Special Health Care Needs.**

**R398-1. Newborn Screening.**

**R398-1-1. Purpose and Authority.**

(1) The purpose of this rule is to facilitate early detection, prompt referral, early treatment, and prevention of mental retardation in infants with certain metabolic disorders.

(2) Authority for the Newborn Screening program and promulgation of rules to implement the program are found in Section 26-10-6.

**R398-1-2. Definitions.**

(1) "Abnormal test result" means a result that is outside of the normal range for a given test.

(2) "Appropriate specimen" means a blood specimen submitted on the Utah Newborn Screening Kit form which conforms with the criteria in R398-1-8.

(3) "Congenital Hypothyroidism" means a disorder in which the newborn is unable to secrete or produce thyroxine normally.

(4) "Department" means the Utah Department of Health.

(5) "Follow up" means the tracking of all newborns with an abnormal result, inconclusive result, inadequate specimen or a QNS specimen through to a normal result or confirmed diagnosis and referral.

(6) "Galactosemia" means a recessively inherited genetic disorder in which the individual is completely or partially incapable of normal metabolism of galactose due to a deficiency of the galactose-1-phosphate uridyltransferase enzyme.

(7) "Inadequate specimen" means a specimen determined by the Newborn Screening Laboratory to be unacceptable for testing.

(8) "Inconclusive result" means a specimen that has no growth on the Gutherie inhibition test for phenylketonuria.

(9) "Institution" means a hospital, alternate birthing facility, or midwife service in Utah which provides maternity or nursery services or both.

(10) "Metabolic diseases" means those diseases due to an inborn error of metabolism, for which the Department of Health shall screen all infants.

(11) "Newborn Screening Kit" means the department's demographic form with attached Food and Drug Administration (FDA)-approved filter paper medical collection device.

(12) "Phenylketonuria" means a recessively inherited genetic disorder in which the individual is completely or partially incapable of normal metabolism of phenylalanine due to a deficiency of the phenylalanine hydroxylase enzyme.

(13) "Practitioner" means a person licensed by the Department of Commerce, Division of Occupational and Professional Licensing to practice medicine, naturopathy, or chiropractic or to be a nurse practitioner, as well as the licensed or unlicensed midwife who takes responsibility for delivery or the health care of a newborn.

(14) "QNS specimen" means a specimen that has been partially tested but requires more blood to complete the full testing.

(15) "Hemoglobinopathy" means a recessively inherited genetic defect of the structure of hemoglobin found in red blood cells.

**R398-1-3. Implementation.**

Each newborn in the state of Utah shall submit to the Newborn Screening testing, except as

provided in Section R398-1-11.

**R398-1-4. Responsibility for Collection of the First Specimen.**

(1) If the newborn is born in an institution, the institution must collect and submit an appropriate specimen, unless transferred to another institution prior to 48 hours of age.

(2) If the newborn is born outside of an institution, the practitioner or other person primarily responsible for providing assistance to the mother at the birth must arrange for the collection and submission of an appropriate specimen.

(3) If there is no other person in attendance of the birth, the parent or legal guardian must arrange for the collection and submission of an appropriate specimen.

(4) If the newborn is transferred to another institution prior to 48 hours of age, the receiving health institution must collect and submit an appropriate specimen.

**R398-1-5. Timing of Collection of First Specimen.**

The first specimen shall be collected between 48 hours and five days of age. Except:

(1) If the newborn is discharged from an institution before 48 hours of age, an appropriate specimen must be collected within four hours of discharge.

(2) If the newborn is to receive a blood transfusion or dialysis, the appropriate specimen must be collected immediately before the procedure, except in emergency situations where time does not allow for collection of the specimen. If the newborn receives a blood transfusion or dialysis prior to collecting the appropriate specimen the following must be done:

(a) Repeat the collection and submission of an appropriate specimen 7-10 days after last transfusion or dialysis for phenylketonuria and congenital hypothyroidism;

(b) Repeat the collection and submission of an appropriate specimen 120 days after last transfusion or dialysis for galactosemia.

**R398-1-6. Parent Education.**

The person who has responsibility under Section R398-1-4 shall inform the parent or legal guardian of the required collection and submission and the disorders screened. That person shall give the second half of the Newborn Screening Kit to the parent or legal guardian with instructions on how to arrange for collection and submission of the second specimen.

**R398-1-7. The Second Specimen.**

A second specimen shall be collected between 7 and 28 days of age.

(1) The parent or legal guardian shall arrange for the collection and submission of the appropriate specimen through an institution, practitioner, or local health department.

(2) If the newborn's first specimen was obtained prior to 48 hours of age, the second specimen shall be collected by fourteen days of age.

(3) If the newborn is hospitalized beyond the seventh day of life, the institution shall arrange for the collection and submission of the appropriate specimen.

**R398-1-8. Criteria for Appropriate Specimen.**

(1) The institution or practitioner collecting the appropriate specimen must:

(a) Use only a Newborn Screening Kit purchased from the department. The fee for the kit is set by the Legislature in accordance with Section 26-1-6;

(b) Correctly store the Newborn Screening Kit;

(c) Not use the Newborn Screening Kit beyond the date of expiration;

(d) Not alter the Newborn Screening Kit in any way;

(e) Complete all information on the Newborn Screening Kit. If the infant is being adopted, the following may be omitted: infant's last name, birth mother's name, address, and telephone number. Infant must have an identifying name, and a contact person must be listed;

(f) Apply sufficient blood to the filter paper;

(g) Not contaminate the filter paper with any foreign substance;

(h) Not tear, perforate, scratch, or wrinkle the filter paper;

(i) Apply blood evenly to one side of the filter paper and be sure it soaks through to the other side;

(j) Apply blood to the filter paper in a manner that does not cause caking;

(k) Collect the blood in such a way as to not cause serum or tissue fluids to separate from the blood;

(l) Dry the specimen properly;

(m) Not remove the filter paper from the Newborn Screening Kit.

(2) Submit the completed Newborn Screening Kit to the Utah Department of Health, Newborn Screening Laboratory, 46 North Medical Drive, Salt Lake City, Utah 84113.

(a) The Newborn Screening Kit shall be placed in an envelope large enough to accommodate it without folding the kit.

(b) If mailed, the Newborn Screening Kit shall be placed in the U.S. Postal system within 24 hours of the time the appropriate specimen was collected.

(c) If hand-delivered, the Newborn Screening Kit shall be delivered within 48 hours of the time the appropriate specimen was collected.

**R398-1-9. Abnormal Result.**

(1) If the department finds an abnormal result, the department shall inform the practitioner noted on the screening specimen form.

(2) The department may require the practitioner to collect and submit additional specimens and conduct additional diagnostic tests.

(3) The practitioner shall collect and submit specimens within the time frame and in the manner instructed by the Department for the particular diagnostic test.

(4) As instructed by the Department or the practitioner, the parent or legal guardian of a newborn identified with an abnormal test result shall promptly take the newborn to the practitioner or the Department to have an appropriate specimen collected.

(5) A medical care provider who makes the final diagnosis shall complete a diagnostic form and return it to the department within 30 days of the notification letter from the Department.

**R398-1-10. Inconclusive Result, Inadequate Specimen, or QNS Specimen.**

(1) If the department finds an inconclusive result, inadequate specimen, or QNS specimen, the department shall inform the practitioner noted on the screening specimen form.

(2) The practitioner shall submit an appropriate specimen in accordance with Section R398-1-8. The specimen shall be collected and submitted within two days of notice, and the form shall be labeled for testing as directed by the department.

(3) The parent or legal guardian of a newborn identified with an inconclusive result, inadequate specimen or QNS specimen shall promptly take the newborn to the practitioner to have an appropriate specimen collected.

**R398-1-11. Testing Refusal.**

A parent or legal guardian may refuse to allow the required testing for religious reasons only. The practitioner or institution shall file in the newborn's record documentation of refusal, reason, education of family about the disorders, and signed waiver by both parents or legal guardian. The practitioner or institution shall submit a copy of the refusal to the Utah Department of Health, Family Health Services, Newborn Screening Program, P.O. Box 144660, Salt Lake City, UT 84114-4660.

**R398-1-12. Access to Medical Records.**

The department shall have access to the medical records of a newborn in order to identify practitioner, reason appropriate specimen was not collected, or to collect missing demographic information.

**R398-1-13. Noncompliance by Parent or Legal Guardian.**

If the practitioner or institution has information that leads it to believe that the parent or legal guardian is not complying with this rule, the practitioner or institution shall report such noncompliance as medical neglect to the department.

**R398-1-14. Test Changes.**

The department, after consulting with the Genetic Advisory Committee, may make additions or changes to the Newborn Screening battery of tests.

**KEY: health care, newborn screening**
**August 7, 2001** **26-1-6**
**Notice of Continuation October 12, 1999** **26-10-6**

NEWBORN SCREENING COLLECTION INSTRUCTIONS

# Please Read This Important Information

FIRST SCREEN.
Specimens should be collected on all newborns between 48 hours and 5 days of age. If newborn is discharged before 48 hours obtain specimen within 4 hours of discharge. **CORD BLOOD IS NOT ACCEPTABLE.**

Invalid results may occur on:
Specimens collected prior to 24 hrs after protein intake.
Specimens collected prior to 48 hrs. of age.
Infants of low birth weight, having transfusion, specimens accompanied by improper or incomplete paper work.

Completion of Form

1. Legibly print all information requested in spaces provided. **USE ONLY BLACK INK AND BLOCK CAPITAL LETTERS.**
2. Enter complete information.
3. Do Not handle filter paper.

MAIL TO: NEWBORN SCREENING LABORATORY
UTAH DEPARTMENT OF HEALTH
46 NORTH MEDICAL DRIVE
SALT LAKE CITY, UT 84113-9903
PHONE: (801) 584-8256

Collection Procedure (Heel Stick)

1. Place limb in dependent position.
2. Cleanse skin with alcohol, DRY, and puncture with disposable lancet.
3. Wipe off first drop of blood.
4. Allow large drop of blood to form. Apply blood directly to filter paper. Apply to one side only and allow to soak through to the other side.
5. Fill all four (4) circles for first screen.
6. Allow specimen to dry thoroughly, 3-4 hours before mailing.

Specimens may be UNSATISFACTORY if:

A. Blood is smeared with liquid.
B. All filled circles are not completely saturated.
C. Filter paper is scratched, torn or wrinkled.
D. Specimen appears to be contaminated.
E. Not enough blood submitted.
F. Clotted or caked blood present on filter paper.
G. Blood applied to both sides.
H. Serum or tissue fluids in blood.
I. Blood is unevenly applied to filter paper.
J. Specimen is too old or age of specimen can not be determined.

Remove this copy before collecting specimen.
This copy may be retained for your records.

I.D. Number 065A800

NEWBORN SCREENING COLLECTION INSTRUCTIONS

# Please Read This Important Information

SECOND SCREEN.
Specimens should be collected between 7 days and 28 days of age.

Invalid results may occur on:
Infants of low birth weight, having transfusion, specimens accompanied by improper or incomplete paper work.

Completion of Form

1. Legibly print all information requested in spaces provided. **USE ONLY BLACK INK AND BLOCK CAPITAL LETTERS.**
2. Enter complete information.
3. Do Not handle filter paper.

MAIL TO: NEWBORN SCREENING LABORATORY
UTAH DEPARTMENT OF HEALTH
46 NORTH MEDICAL DRIVE
SALT LAKE CITY, UT 84113-9903
PHONE: (801) 584-8256

Collection Procedure (Heel Stick)

1. Place limb in dependent position.
2. Cleanse skin with alcohol, DRY, and puncture with disposable lancet.
3. Wipe off first drop of blood.
4. Allow large drop of blood to form. Apply blood directly to filter paper. Apply to one side only and allow to soak through to the other side.
5. Fill three (3) circles for second screen.
6. Allow specimen to dry thoroughly, 3-4 hours before mailing.

Specimens may be UNSATISFACTORY if:

A. Blood is smeared with liquid.
B. All filled circles are not completely saturated.
C. Filter paper is scratched, torn or wrinkled.
D. Specimen appears to be contaminated.
E. Not enough blood submitted.
F. Clotted or caked blood present on filter paper.
G. Blood applied to both sides.
H. Serum or tissue fluids in blood.
I. Blood is unevenly applied to filter paper.
J. Specimen is too old or age of specimen can not be determined.

Remove this copy before collecting specimen.
This copy may be retained for your records.

I.D. Number 065A800

065A800

PLACE LABEL HERE

FOR UDOH LAB ONLY - DO NOT MARK

065A800

PLACE LABEL HERE

FOR UDOH LAB ONLY - DO NOT MARK

UTAH DEPARTMENT OF HEALTH NEWBORN SCREENING FORM

FIRST SCREEN (for Phenylketonuria, Galactosemia, Congenital Hypothyroidism, Hemoglobinopathy)

*BLOCK PRINT ALL CAPITALS* - COMPLETE ENTIRE FORM

FORM EXPIRES NOVEMBER 2003

02-10-2002
Sample collection date MM/DD/YYYY

094763
Medical Record Number

GAMGEET
Baby's last name

Baby's first name

○ M ☒ F

BYWATER HOS
Birthplace/Hospital

02-08-2002
Baby's Birthdate MM/DD/YYYY

☒ Breast ○ Adopted ○ Transfusion date:

○ Bottle ○ Premature/sick

2542
Birthweight (gms)

GAMGEET
Mother's last name

ROSE
Mother's first name

COTTON
Mother's maiden name

123 S BAG END
Mother's mailing address

HOBBITTON
City

UT
State

84848
Zip

07-15-1982
Mother's Birthdate MM/DD/YYYY

801-577-5757
Mother's Area Code & phone

BRAWLYBUCK MERIDOC
Doctor's Name / Clinic's Name

123 SMIALS STE 3
Doctor's / Clinic's Address

FROGMORTON
City

UT
State

84888
Zip

801-577-7757
Doctor's / Clinic's Area Code & Phone

BELOW FOR UDOH LAB ONLY - DO NOT MARK

Sample Unacceptable ▶ ○

065A800

PLACE LABEL HERE

FOR UDOH LAB ONLY - DO NOT MARK

065A800

PLACE LABEL HERE

FOR UDOH LAB ONLY - DO NOT MARK

UTAH DEPARTMENT OF HEALTH NEWBORN SCREENING FORM

SECOND SCREEN (for Phenylketonuria, Congenital Hypothyroidism)

*BLOCK PRINT ALL CAPITALS* - COMPLETE ENTIRE FORM

FORM EXPIRES NOVEMBER 2003

03-04-2002
Sample collection date MM/DD/YYYY

XC344
Medical Record Number

ELAND R
Baby's first name

○ M ☒ F

GAMGEET
Baby's last name

BYWATTER HOS
Birthplace/Hospital

02-08-2002
Baby's Birthdate MM/DD/YYYY

☒ Breast ○ Adopted ○ Transfusion date:

○ Bottle ○ Premature/sick

2542
Birthweight (gms)

GAMGEET
Mother's last name

ROSET
Mother's first name

COTTON
Mother's maiden name

123 S BAG END
Mother's mailing address

HOBBITTON
City

UT
State

84848
Zip

07-15-1982
Mother's Birthdate MM/DD/YYYY

801-577-5757
Mother's Area Code & phone

TOOK PIEREGRIM
Doctor's Name / Clinic's Name

123 SMIALS STE 3
Doctor's / Clinic's Address

FROGMORTON
City

UT
State

84888
Zip

801-577-7757
Doctor's / Clinic's Area Code & Phone

RECALL SCREEN MARK ONLY IF INSTRUCTED

○ Unacceptable 1st 2nd ○ Positive for: GAL CHYP PKU HB

BELOW FOR UDOH LAB ONLY - DO NOT MARK

Sample Unacceptable ▶ ○

NEWBORN SCREENING COLLECTION INSTRUCTIONS

# Please read this important information

MISCELLANEOUS Newborn Screening form. First screen specimens should be collected on all newborns between 48 hours and 5 days of age. If newborn is discharged before 48 hours obtain specimen within 4 hours of discharge. A second screen is required between 7 days and 28 days of age.

Invalid results may occur on: Infants of low birth weight, having transfusion, specimens accompanied by improper or incomplete paper work.

## Completion of Form

1. Legibly print all information requested in spaces provided. USE ONLY BLACK INK AND BLOCK CAPITAL LETTERS.
2. Enter complete information.
3. Do Not handle filter paper.
4. Use the "test requested" box to indicate which screen (first or second) needs to be run.
5. If using this form to replace a lost or unusable kit form, cross out the miscellaneous number and write in original kit number.
6. Mail To: NEWBORN SCREENING LABORATORY
   UTAH DEPARTMENT OF HEALTH
   46 N MEDICAL DR
   SALT LAKE CITY UT 84113-9903

## Collection Procedure (HEEL STICK)

1. Place limb in dependent position.
2. Cleanse skin with alcohol, DRY, and puncture with disposable lancet.
3. Wipe off first drop of blood.
4. Allow large drop of blood to form. Apply blood directly to filter paper. Apply to one side only and allow to soak through to the other side.
5. Fill all four (4) circles for first screen; three (3) circles for second screen.
6. Allow specimen to dry thoroughly, 3-4 hours before mailing.

## Specimens may be UNSATISFACTORY if:

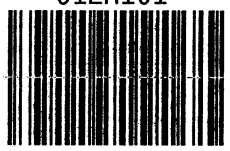
A. Blood is smeared with liquid.
B. All filled circles are not completely saturated.
C. Filter paper is scratched, torn or wrinkled.
D. Specimen appears to be contaminated.
E. Not enough blood is submitted.
F. Clotted or caked blood present on filter paper.
G. Blood applied to both sides.
H. Serum or tissue fluids in blood.
I. Blood is unevenly applied to filter paper.
J. Specimen is too old or age of specimen can not be determined.

Remove this copy before collecting specimen.

This copy may be retained for your records.

I.D. Number 012M101

065A800
~~012M101~~



~~012M101~~
065A800

PLACE LABEL HERE
FOR UDOH LAB ONLY - DO NOT MARK

PLACE LABEL HERE
FOR UDOH LAB ONLY - DO NOT MARK

UTAH DEPARTMENT OF HEALTH NEWBORN SCREENING FORM
MISCELLANEOUS SCREEN
*BLOCK PRINT ALL CAPITALS* - COMPLETE ENTIRE FORM

**FORM EXPIRES NOVEMBER 2003**

X C 3 4 4 — Medical Record Number
0 3 - 1 4 - 2 0 0 2 — Sample collection date MM/DD/YYYY

G A M G E E — Baby's last name
E L A W O R — Baby's first name
○ M ✕ F

B Y W A T E R H O S — Birthplace/Hospital
0 2 - 0 8 - 2 0 0 2 — Birthdate MM/DD/YYYY

✕ Breast ○ Adopted ○ Transfusion date:
○ Bottle ○ Premature/sick
2 5 4 2 — BIRTHWEIGHT (gms)

G A M G E E — Mother's last name
R O S E — Mother's first name

C O T T O N — Mother's maiden name

1 2 3 S B A G E M O — Mother's mailing address

H O B B I T O N — City
U T — State
8 4 8 4 8 — Zip

0 7 - 1 5 - 1 9 8 2 — Mother's Birthdate MM/DD/YYYY
8 0 1 - 5 7 7 - 5 7 5 7 — Mother's Area Code & phone

T O O K P E R E G R I N — Doctor's Name / Clinic Name

1 2 3 S M I A L S S T E 3 — Doctor's / Clinic's Address

F R O G M O R T O N — City
U T — State
8 4 8 8 8 — Zip

— Doctor's / Clinic's Area Code & Phone

**TEST REQUESTED** – Mark One

○ First Screen (PKU, GAL, CHYP, HB) ✕ Second Screen (PKU, CHYP)

**RECALL SCREEN MARK ONLY IF INSTRUCTED**

○ Unacceptable 1st 2nd ○ Positive for: GAL CHYP PKU HB ○ POST-TRANSFUSION

**BELOW FOR UDOH LAB ONLY - DO NOT MARK**

Sample Unacceptable ▶ ○

L-8929301